

Baxter

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

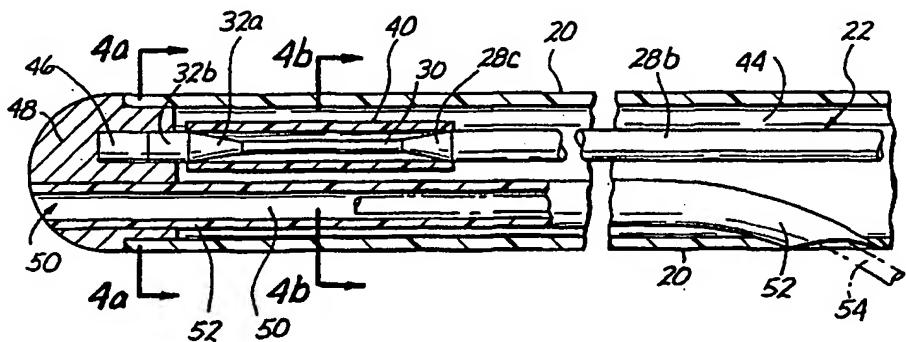


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/22, G10K 11/24	A1	(11) International Publication Number: WO 95/10233
		(43) International Publication Date: 20 April 1995 (20.04.95)

(21) International Application Number: PCT/US94/11550	(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 11 October 1994 (11.10.94)	Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(30) Priority Data: 08/135,275 12 October 1993 (12.10.93) US	
(71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Dearfield, IL 60015-4633 (US).	
(72) Inventor: NITA, Henry; 26051 Malaga Lane, Mission Viejo, CA 92692 (US).	
(74) Agents: SUN, Raymond et al.; P.O. Box 15210, Irvine, CA 92713-5210 (US).	

(54) Title: **ULTRASOUND TRANSMISSION MEMBER HAVING IMPROVED LONGITUDINAL TRANSMISSION PROPERTIES**



(57) Abstract

An elongate ultrasound transmission member (22) having regions (26, 28, 30, 32) of differing cross-sectional dimension or diameter. A sleeve, sheath or other damping member (40) may be positioned around a portion (30) of the ultrasound transmission member (22) to dampen or limit transverse side-to-side movement of such portion (30) of the member (22). The ultrasound transmission member (22) may be incorporated into a flexible catheter body (20) to form an ultrasound delivering medical catheter (10).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

**ULTRASOUND TRANSMISSION MEMBER HAVING IMPROVED
LONGITUDINAL TRANSMISSION PROPERTIES**

Field of the Invention

5 The present invention relates generally to medical devices and more particularly to an improved ultrasound transmission member for transmitting ultrasonic energy from an extracorporeal ultrasound generating device to a location within a mammalian body.

10 **Related Application**

This patent application is a continuation-in-part of United States Patent Application 07/640,190 entitled ULTRASONIC ANGIOPLASTY DEVICE INCORPORATING IMPROVED TRANSMISSION MEMBER AND ABLATION PROBE, filed on January 15, 1991, the entire disclosure of which is expressly incorporated herein by reference.

Background of the Invention

The prior art has included a number of ultrasonic devices for ablating, destroying or removing obstructive material within anatomical structures of the body, such as blood vessels. Examples of devices which purportedly utilize ultrasonic energy, alone or in conjunction with other treatment modalities, to remove obstructions from anatomical structures include those described in United States Patent Nos. 3,433,226 (Boyd), 3,823,717 (Pohlman, et al.), 4,808,153 (Parisi), 4,936,281 (Stasz), 3,565,062 (Kuris), 4,924,863 (Sterzer), 4,870,953 (Don Michael, et al.), 4,920,954 (Alliger, et al.), and 5,100,423 (Fearnott) as well as other patent publications WO87-05739 (Cooper), WO89-06515 (Bernstein, et al.), WO90-0130 (Sonic Needle Corp.), EP316789 (Don Michael, et al.), DE3,821,836 (Schubert) and DE2,438,648 (Pohlman).

In particular, flexible ultrasound-delivering catheters have been utilized to recanalize blood vessels

which have become obstructed by atherosclerotic plaque and/or thrombotic matter.

Previously filed United States Patent Application S.N. 07/640,190, entitled ULTRASONIC ANGIOPLASTY DEVICE 5 INCORPORATING IMPROVED TRANSMISSION MEMBER AND ABLATION PROBE, of which this application is a continuation-in-part, describes percutaneously insertable ultrasound delivering catheters which are useable to ultrasonically ablate or remove obstructive matter from blood vessels. As disclosed 10 in patent application s.n. 07/640,190, such ultrasound delivery catheters may be constructed of a flexible catheter sheath having an elongate ultrasound transmission member or wire extending longitudinally therethrough. The cross-sectional dimension of the ultrasound transmission 15 member may be tapered or narrowed near the distal end of the member. While such tapering or narrowing of the cross-sectional diameter of the ultrasound transmission member will typically decrease its rigidity and improve its bendability at the region of the taper or narrowing, such 20 tapering or narrowing of the ultrasound transmission member carries with it a resultant increase in amplitude of the ultrasonic energy being transmitted through such narrowed or tapered region. Such increase in amplitude at the narrowed or tapered region may give rise to an increased 25 likelihood of breakage or fracture of the ultrasound transmission member.

To facilitate use of ultrasonic ablation techniques within small tortuous blood vessels or other anatomical structures, it is desirable to develop small-diameter 30 ultrasound-delivery catheters which are sufficiently pliable and bendable, at least in their distal regions, to navigate tortuous anatomical configurations without undue likelihood of breakage or fracture of the ultrasound transmission member during use.

In view of the foregoing, there remains a need in the art for development of new ultrasound transmission members having improved pliability or bendability with minimal likelihood of breakage or fracture.

5 Summary of the Invention

In accordance with the present invention, there is provided an ultrasound transmission member having at least four regions of differing cross-sectional dimension. The main proximal region of the member is of substantially 10 continuous first cross-sectional dimension or diameter. The second region of the member extends distally from the distal end of the first region thereof, and is downwardly tapered to a (continuously or in a step-wise fashion) from said first cross-sectional dimension to a second cross- 15 sectional dimension smaller than said first cross-sectional dimension. A third region of the member extends distally from the distal end of the second region and is of a substantially continuous cross-sectional dimension preferably equal to said second cross-sectional dimension. 20 The fourth region of the member extends distally from the distal end of the third region and is outwardly tapered (continuously or in a step-wise fashion) to a fourth cross-sectional dimension, said fourth cross-sectional dimension being larger than the continuous cross-sectional dimension 25 of said third region.

Further in accordance with the invention, a sleeve, sheath or other damping member may be positioned around the third region of the ultrasound transmission member to dampen or limit transverse side-to-side vibration of the 30 third region during operation.

Still further in accordance with the invention, the ultrasound transmission member may be formed of various materials including superelastic metal alloy. A presently preferred superelastic metal alloy is a nickel titanium

alloy containing 50.8 atomic per cent nickel/balance titanium.

Still further in accordance with the invention, the ultrasound transmission member of the foregoing character 5 may be incorporated into a flexible ultrasound catheter, said ultrasound catheter being insertable into a blood vessel or other anatomical structure for purposes of delivering ultrasonic energy to an anatomical structure within the mammalian body.

10 Still further in accordance with the invention, the ultrasound transmission member of the foregoing character may be incorporated into a guidewire, or other elongate housing or body for purposes of carrying ultrasonic vibration therethrough.

15 Further objects and advantages of the invention will become apparent to those skilled in the art upon reading and understanding of the following detailed description and the accompanying drawings.

Brief Description of the Drawings

20 Figure 1 is a perspective view of an ultrasound catheter device of the present invention operatively connected to an ultrasound generating system.

Figure 2 is an enlarged perspective view of the distal end of the ultrasound catheter of Figure 1 having a 25 guidewire (phantom lines) extending therethrough.

Figure 3 is a longitudinal sectional view of the distal portion of the catheter shown in Figure 1.

Figure 4a is a cross-sectional view through Line 4a-4a of Figure 3.

30 Figure 4b is a cross-sectional view through Line 4b-4b of Figure 3.

Figure 5 is a broken elevational view of the preferred ultrasound transmission member of the present invention.

Figure 6 is a side elevational view of a portion of the ultrasound transmission member of Figure 5 having a damping member or sleeve positioned thereon.

Figure 7 is a longitudinal sectional view of a portion 5 of the proximal end connector assembly of the catheter shown in Figure 1.

Detailed Description of the Preferred Embodiment

The following detailed description and the accompanying drawings are intended to describe and 10 illustrate presently preferred embodiments of the invention only and are not intended to limit the scope of the invention in any way. Specifically, the hereafter described embodiments and drawings are not intended to comprehensively describe or show all of the possible 15 embodiments of the claimed invention.

A. A Preferred Ultrasound Catheter Incorporating An Ultrasound Transmission Member Of The Present Invention

As shown in Figure 1, an ultrasonic catheter 10 of the present invention may be utilized by coupling the 20 ultrasonic catheter 10 to an ultrasound generating system 12. The ultrasound generating system 12 comprises a signal generator 14 (e.g., Model UAG.1110, Baxter Healthcare Corp., Edwards LIS Division, Irvine, California) connected, by way of cable 16 to an ultrasound transducer 18 (e.g., 25 Model UAT-1000, Baxter Healthcare Corporation, Edwards LIS Division, Irvine, California), which is operable to convert the electrical signal into ultrasonic vibration.

The ultrasound catheter 10 of the present invention comprises an elongate flexible catheter body 20 having an 30 elongate ultrasound transmission member or wire 22 extending longitudinally therethrough. A proximal end

connector assembly 24 is positioned on the proximal end of the catheter body 10. As shown in detail in Figure 7 the proximal connector assembly 24 is configured to facilitate connection of the proximal end of the ultrasound 5 transmission member 22 to the ultrasound transducer 18 such that ultrasonic vibration from the transducer 18 will be transmitted, distally, through the ultrasound transmission member 22 to the distal end of the catheter 10.

The ultrasound transmission member 22 of the present 10 invention may be formed of any suitable material capable of carrying ultrasonic energy from the proximal end of the catheter 10 to the distal end thereof. In particular, the presently preferred embodiment of the ultrasound transmission member 22 of the present invention is formed 15 of nickel-titanium alloy which exhibits super elastic properties within the temperature range under which the device is operated.

In particular, one presently preferred superelastic metal alloy of which the ultrasound transmission member 22 20 may be formed is nickel-titanium alloy consisting of 50.8 atomic percent nickel/balance titanium and is commercially available as Tinel™ BB from Raychem Corporation, Menlo Park, California.

The physical properties of the preferred 50.8 atomic per 25 cent nickel NiTi alloy are as follows:

-7-

Properties of NiTi Alloy
Having 50.8 At.% Nickel/Balance Titanium

Property *	Units	Value
5 Superelastic Temperature Range	°C	20 to 80
10 Loading Plateau Stress (at 20°C)	Mpa	480
15 Unloading Plateau Stress	Mpa	135
20 Permanent Set (at 20°C after 8% strain)	%	0.2
25 Ultimate Tensile Strength (at 20°C)	Mpa Ksi	1150 170
30 Elongation at Failure	%	10
35 Melting Point	°C	1350
40 Density	g/cm lbs/cu.Inch	6.5 0.235

20 *Typical Values for Cold Worked and Shape Set Condition

Examples of superelastic metal alloys which are useable to form the ultrasound transmission member 22 of the present invention is described in detail in the United States Patent Nos. 4,665,906 (Jervis); 4,565,589 (Harrison); 4,505,767 (Quin); and 4,337,090 (Harrison). The disclosures of United States Patents Nos. 4,665,906; 4,565,589; 4,505,767; and 4,337,090 are expressly incorporated herein by reference insofar as they describe the compositions, properties, chemistries, and behavior of specific metal alloys which are superelastic within the temperature range at which the ultrasound transmission member 22 of the present invention operate, any and all of which superelastic metal alloys may be useable to form the superelastic ultrasound transmission member 22.

In the preferred embodiment, the ultrasound transmission member 22 is specifically configured and constructed to provide desirable flexibility or bendability near the distal end of the catheter, while at the same time 5 minimizing the likelihood of breakage or fracture of the ultrasound transmission member 24 during use.

For example, one preferred configuration is shown in Figure 5 for an ultrasound transmission member 22 of the present invention having an overall length of 63. As 10 shown, the ultrasound transmission member 22 having an overall length of 63 inches comprises a) a first (proximal) region 26, b) a second region 28 extending distally from the first proximal region 26, c) a third region 30 extending distally from the second region 28, and d) a 15 fourth region 32 extending distally from the third region 30.

The first (proximal) region 26 of the ultrasound transmission member 22 constitutes the main proximal portion of the member 22, and extends approximately 50.5 20 inches from the proximal end thereof. The outer diameter D1 of the first portion 26 is approximately 0.030 inches and is substantially continuous over its entire length.

The second region 28 is about 6.2 inches in overall length and is downwardly tapered, from an outer diameter 25 equal to D1 at its proximal end, to a smaller outer diameter D2 at its distal end. The tapering or narrowing of the second region 28 may be gradually continuous or may be formed in steps, as shown in Figure 5. Specifically, as 30 shown in Figure 5, the second region 28 includes first 28A, second 28B and third 28C subregions. The first subregion 28A is gradually tapered from diameter D1 to an intermediate diameter D1.5 between D1 and D2. The second subregion 28B is of substantially continuous intermediate diameter D1.5 over its entire length. The third subregion

28C is then further downwardly tapered to a diameter of D2, as shown.

The third region 30 of the ultrasound transmission member 22 is of continuous diameter D3 over its entire 5 length of approximately 0.750 inches. Diameter D3 is the same as diameter D2 at the distal end of the second region 28.

The fourth region 32 of the ultrasound transmission wire 22 is outwardly tapered or enlarged from diameter D3 10 at its proximal end to diameter D4 at its distal end. The fourth region 32 of the ultrasound transmission member 22 may be of a gradually continuous taper or may include multiple subregions, as shown in Figure 5. Specifically, as shown in Figure 5, the fourth region 32 has an overall 15 length of 0.300 inches and comprises a first subregion 32A and a second subregion 32B. In the embodiment shown, the first subregion 32A is gradually tapered from diameter D3 to diameter D4. The second subregion 32B is of substantially continuous outer diameter D4. Diameter D4 is 20 approximately 0.014 inches.

Because the third region 30 of the ultrasound transmission member 22 is of minimal diameter D3, such third region 30 is subject to exaggerated lateral or side-to-side vibration during use. In order to dampen or limit 25 the lateral side-to-side vibration of the third region 30, an external damping member, such as a sheath 40, may be applied to such region 30 to limit its propensity for lateral side-to-side movement. As shown in Figure 6, the preferred sheath member 40 comprises a segment of plastic 30 tubing surrounding the entire third region 30 of ultrasound transmission member 22. The inner diameter (ID) of sheath member 40 is sized relative to the ultrasound transmission member 22 such that the proximal and distal ends of the sheath member 40 are flush with and engage the adjacent 35 outer surfaces of the second region 28 and fourth region 32

of the ultrasound transmission member 22, as shown. Adhesive 42 is utilized to bond, at least the end portions of sheath member 40 to the adjacent outer surfaces of the ultrasound transmission member 22.

5 The inner diameter of sheath 40 is larger than the outer diameter of third region 30 such that a space 44 exists therebetween. Space 45 may optionally be filled with matter capable of damping or inhibiting lateral side-to-side movement of the third region 30. Examples of
10 damping material which may be disposed within space 45 include RTV silicone (product code, manufacturer, city, state) or other elastic materials such as natural or synthetic rubber. As an alternative, the quantity of adhesive 42 may be increased such that the adhesive 42
15 fills the entire space 45 between the outer surface of the third region 30 and the inner diameter of sheath 40. In such embodiments, it will be recognized that adhesion of the adhesive 42 to the outer surface of the third region 30 may limit the desirable longitudinal vibration of the third
20 region 30, in addition to the undesirable lateral or side-to-side vibration thereof. To avoid such adhesion to the third region 30, anti-adhesive materials or release agents may be applied to the third region 30 prior to disposition of the adhesive 42, thereby preventing the adhesive 42 from
25 adhering to the outer surfaces of the third region 30, while permitting the adhesive to form the desirable bond with the adjacent surfaces of the second region 28 and fourth region 32 so as to hold sheath 40 firmly in place.

As shown in Figures 3-4, the catheter body comprises
30 a hollow tube having a longitudinal bore or lumen 44 extending therethrough. A rigid distal head or endcap 48 is inserted to the distal end of the catheter body 20. In the embodiment shown, the distal head 40 has a generally smooth rounded outer configuration so as to form a blunt
35 tip which is flush and continuous with the adjacent outer

surface of the catheter body 20. A blind cul de sac or bore 46 is formed in the proximal side of the distal head 48 to receive the distal end of the ultrasound transmission member 22 therein. As shown, the distal end of the 5 ultrasound transmission member 22 is inserted part way into bore 46 and may be welded, adhered or mechanically engaged thereto so as to hold distal head 48 in its desired longitudinal position within the distal end of the catheter body 20 and also to form abutting contact between the 10 distal end of the ultrasound transmission member 22 and the distal head 48. As such, ultrasonic vibration which passes distally through the ultrasound transmission member 22 will be transmitted into the distal head 48, thereby causing distal head 48 to vibrate in accordance with the energy 15 transmitted through ultrasound transmission member 22.

Also in the embodiment of the catheter shown in Figures 3-4, a guidewire lumen 50 extends through the distal head 48 and partially through a distal portion of the catheter body. A guidewire (phantom lines) may be 20 passed through the guidewire lumen to facilitate insertion and positioning of the catheter 10.

The guidewire lumen 50 is at least partially defined by the inner lumen of a tube 52. The guidewire lumen 50 extends through a longitudinal bore formed in the distal 25 head 48 and through a distal portion of the lumen 44 of the catheter body 20. The proximal end of tube 52 is flush with and may be bonded to the sidewall of the catheter 20, thereby forming sidewall guidewire aperture 54 in catheter body 20.

30 Also, in the embodiment shown, dual infusion apertures 56 extend longitudinally through distal head 48 in fluidic communication with the hollow bore 44 of catheter 20. A fluid infusion sidearm 58 is formed in the proximal end connector assembly 24 to permit infusion of fluid through 35 the bore of the proximal connector assembly 24 and through

the hollow lumen 44 of the catheter 20 such that said fluid will pass out of the dual infusion apertures 55 located in the distal head 48 of the device. Such passage of fluid through the catheter 20 may be for purposes of cooling or 5 controlling the temperature of the ultrasound transmission member 22 and/or may also be for purposes of providing an infusion of irrigation fluid, radiographic contrast media, oxygenated perfusate and/or medicaments.

One type of proximal connector assembly 24 which may 10 be utilized as part of the catheter device 10 is shown, in detail, in Figure 7. The proximal connector assembly 24 shown in Figure 7 comprises an elongate, rigid body 56 defining a frontal portion 58, a mid-portion 60 and a rear portion 62. The frontal portion 58 of the elongate body 56 15 is firmly connected to the proximal end of the catheter body 20 by way of a threaded gripping member 64 engaged thereto. In this respect, the proximal end of the catheter portion 11 preferably has a flared configuration and includes an annular flange formed on the outermost end 20 thereof which is brought into sealed engagement with the connector assembly 12 when the gripping member 64 is threadably engaged to the body 56. The proximal end of the frontal portion 58 is connected to the distal end of the mid-portion 60 of the elongate body 56 by way of a second 25 gripping member 66. As will be recognized, to facilitate the aforementioned construction, threads are formed on the distal ends of the frontal portion 58 and the mid-portion 60. Additionally, as seen in Figure 7, the proximal end of the mid-portion 60 is non-threaded and is slideably 30 received into a corresponding bore formed in the distal end of the rear portion 62 of the body 56. In this respect, the mid-portion 60 is maintained in engagements to the rear portion 62 via the utilization of an adhesive or other suitable affixation method.

Referring further to Figure 7, the rear portion 62 of the body 56 comprises a distal member 68, the distal end of which is adapted to receive the proximal end of the mid-portion 60, and a generally frusto-conical proximal member 5 70. The proximal end of the distal member 68 is formed of a reduced diameter and is slideably inserted into a complimentary recess defined in the distal end of the proximal member 70. The proximal member 70 is maintained in engagement to the distal member 68 via the utilization 10 of a threaded fastener 72 such as a screw which is extended through the bore defining wall of the proximal member 70 and into a threaded aperture disposed within the reduced diameter proximal end of the distal member 68. The ultrasound transmission member 22 extend longitudinally 15 through the entire catheter portion 11 and through the proximal end of the connector assembly 12. The ultrasound transmission members 22 are then inserted into and engaged by a threaded proximal connector 74 which is positioned within a cylindrical recess formed in the proximal end of 20 the proximal member 70. The ultrasound transducer 18 is cooperatively engaged to the proximal connector 74 in a manner adapted to accomplish the passage of ultrasonic energy through the ultrasound transmission member 22 in a distal direction to the distal end of the catheter body 20.

25 The extreme proximal end of the proximal member 70 is provided with a sonic connector assembly or apparatus configured to effect operative attachment of the proximal ends of the ultrasound transmission member 22 to the horn of the ultrasound transducer 18. The sonic connector 30 assembly or apparatus is preferably configured and constructed to permit passage of ultrasound energy through the ultrasound transmission member 22 with minimal lateral side-to-side movement of the ultrasound transmission members 22 while, at the same time, permitting unrestricted 35 longitudinal forward/backward vibration or movement of the

ultrasound transmission member 22. Specifically, a distal portion of the body of the threaded proximal connector 74 is configured to receive therein a compressible gripping ferrule 76. The compressible gripping ferrule 76 has a 5 small central aperture formed therethrough through which the ultrasound transmission member 22 passes, as shown. A frontal member 78 is threadably tightened within the frontal portion of the body of the proximal connector 74 so as to compress the gripping ferrule 76, thereby causing the 10 gripping ferrule 76 to firmly grip and hold the ultrasound transmission member 22 in place within the body of the proximal connector 74. The proximal connector 74 may then be compressed or crimped inwardly so as to be additionally crimp connected or crimp fit to the proximal ends of the 15 ultrasound transmission member 22, thereby providing further gripping and attachment of the sonic connector assembly to the proximal ends of the ultrasound transmission member 22. The proximal connector 74 is further formed to permit the distal end of the ultrasound 20 transducer horn to be releasably engaged thereto and thus releasably attached to the sonic connector assembly. Thus, the frontal member 78, gripping ferrule 76, and proximal connector 74 combine to form a sonic connector assembly to which the horn of the ultrasound transducer 18 may be 25 attached and through which the ultrasonic energy may be transmitted into the ultrasound transmission member 22. A lumen 80 extending through the rear and mid-portions 62, 60 of the connector assembly 24 is specifically sized to be large enough to permit the ultrasound transmission member 30 22 to pass therethrough with a small amount of space remaining between the outer surfaces of the ultrasound transmission member 24 and the innerlumenal surface of the lumen. Also disposed within the mid-portion receiving bore formed in the distal end of the distal member 68 is an O- 35 ring 82 which is used to prevent the passage of any fluid

along the outer surfaces of the lumen 80 into the proximal member 70 of the rear portion 62.

B. Operation of the Preferred Embodiment

In operation, the catheter 20 described hereabove may
5 be inserted percutaneously, or otherwise, into a desired anatomical structure such as a blood vessel. The proximal connector assembly 24 of the device will then be connected to ultrasound transducer 18. Depression of on/off foot pedal 59 will cause signal generator 14 to emit a desired
10 electrical signal through cable 16 to ultrasound transducer 18. Ultrasound transducer 18 will convert the received electrical signal to ultrasonic vibration and such ultrasonic vibration will be passed through ultrasound transmission member 22 to the distal head 48 of the
15 catheter 10.

As the ultrasonic energy passes from the first region 26 of the ultrasound transmission member 22 into the second region 28 thereof, the narrowing or taper of the second region 28 will result in an increase in the amplitude of
20 the ultrasonic energy passing therethrough. Thereafter, as the ultrasonic energy passes through the constant diameter third region 30 of the ultrasound transmission member 22 the amplitude will remain substantially constant. Thereafter, as the ultrasound energy passes from the third
25 region 30 to the outwardly tapered or enlarging fourth region 32, the amplitude of the ultrasound will again decrease in accordance with the change in outer diameter of the ultrasound transmission member 22.

Although the invention has been described herein with
30 specific reference to presently preferred embodiments thereof, it will be appreciated by those skilled in the art that various additions, modifications, deletions and alterations may be made to such preferred embodiments without departing from the spirit and scope of the
35 invention. For example, the ultrasound transmission member

of the present invention may be positioned within many different catheters which differ in configuration and construction from the preferred catheter shown in this patent application or, the ultrasound transmission member 5 of the present invention may be positioned in, or incorporated in, a guidewire or may be utilized independent of any surrounding catheter sheath as described herein with respect to the preferred embodiment. Accordingly, it is intended that all reasonably foreseeable additions, 10 deletions, alterations and modifications be included within the scope of the invention as defined in the following claims.

WHAT IS CLAIMED IS:

1. An ultrasound transmission member coupleable to an ultrasound generating device for transmitting ultrasound from said ultrasound generating device to a location within 5 a mammalian body, said ultrasound transmitting member comprising:

an elongate member having a proximal end, distal end, and at least four regions of differing cross-sectional dimension, said four regions of said 10 elongate member comprising:

i) a first region extending distally from the proximal end of the member and having a substantially continuous first cross-sectional dimension;

15 ii) a second region extending distally from the distal end of said first region, said second region being tapered to a second cross-sectional dimension smaller than said first cross-sectional dimension;

20 iii) a third region extending distally from the distal end of said second region, said third region being of a substantially continuous third cross-sectional dimension, said third cross-sectional dimension being substantially the same 25 as said second cross-sectional dimension; and

iv) a fourth region extending distally from, the distal end of said third region, said fourth region being tapered to a fourth cross-sectional dimension larger than said third cross-sectional dimension.

30 2. The ultrasound transmission member of Claim 1 wherein said second region further comprises:

a first proximal portion tapered from said first cross-sectional dimension to an intermediate cross-

sectional dimension between said first cross-sectional dimension and said second cross-sectional;

5 an intermediate portion of substantially consistent cross-sectional dimension equal to said intermediate cross-sectional dimension; and

 a distal portion further tapered from said intermediate cross-sectional dimension to said second cross-sectional dimension.

10 3. The ultrasound transmission member of Claim 1 wherein said second region comprises a continuous gradual taper from said first cross-sectional dimension to said second cross-sectional dimension.

 4. The ultrasound transmission member of Claim 1 wherein said fourth region further comprises:

15 a first proximal portion tapered from said third cross-sectional dimension to said fourth cross-sectional dimension; and

20 a distal portion of substantially continuous cross-sectional dimension equal to said fourth cross-sectional dimension.

 5. The ultrasound transmission member of Claim 1 wherein said first segment is approximately 53.0 inches in length.

25 6. The ultrasound transmission member of Claim 1 wherein said first cross-sectional dimension is approximately 0.030 inches diameter.

 7. The ultrasound transmission member of Claim 1 wherein said second region is approximately 8.95 inches in length.

30 8. The ultrasound transmission member of Claim 1 wherein said second cross-sectional dimension is approximately 0.14 inches diameter.

 9. The ultrasound transmission member of Claim 1 wherein said third region is approximately 0.750 inches in length.

10. The ultrasound transmission member of Claim 1 wherein said third cross-sectional dimension is approximately 0.10 inches diameter.

11. The ultrasound transmission member of Claim 1
5 wherein said fourth region is approximately 0.300 inches in length.

12. The ultrasound transmission member of Claim 1 wherein said fourth cross-sectional dimension is approximately 0.014 inches diameter.

10 13. The ultrasound transmission member of Claim 2 wherein said first cross-sectional dimension of said first region is 0.030 and wherein:

15 said first proximal portion of said second region is tapered downwardly from said first cross-sectional dimension of 0.030 inches to an intermediate cross-sectional dimension of 0.014 inches;

said intermediate portion of said second region is of substantially continuous cross-sectional dimension of 0.014 inches; and.

20 said distal portion of said second region is further downwardly tapered from said intermediate cross-sectional dimension of 0.014 inches to said second cross-sectional dimension of 0.010 inches.

14. The ultrasound transmission member of Claim 2
25 wherein:

said first proximal portion of said second region is approximately 2.5 inches in length;

said intermediate portion of said second region is approximately 6.20 inches in length; and

30 said distal portion of said second region is approximately 0.250 inches in length.

15. The ultrasound transmission member of Claim 4 wherein said third cross-sectional dimension of said third region is approximately 0.10 inches and wherein:

5 said first proximal portion of said fourth region
is gradually tapered from said third cross-sectional
dimension of approximately 0.10 inches to a fourth
cross-sectional dimension of approximately 0.014
inches; and

 said distal portion of said fourth region is
continuously of said fourth cross-sectional dimension
of approximately 0.014 inches.

10 16. The ultrasound transmission member of Claim 4
wherein:

 said first proximal portion of said fourth region
is approximately 0.250 inches in length; and

 said second distal portion of said fourth region
is approximately 0.50 inches in length.

15 17. The ultrasound transmission member of Claim 1
further comprising:

20 a dampening member disposed about said third
region to dampen transverse side-to-side vibrational
movement in said third region.

 18. The ultrasound transmission member of Claim 17
wherein said dampening member comprises a tube surrounding
said third region.

25 19. The ultrasound transmission member of Claim 18
wherein said tube is affixed to said ultrasound
transmission member by way of adhesive.

 20. The ultrasound transmission member of Claim 18
wherein said tube is slightly longer than said third
region, said tube having a proximal end in abutting contact
30 with the adjacent second region and a distal end in
abutting contact with the adjacent the fourth region.

 21. The ultrasound transmission member of Claim 18
wherein said tube has a hollow inner bore which is larger
than said third cross-sectional dimension of said third

region such that space exists between said third region and said tube.

22. The ultrasound transmission member of Claim 21 wherein a quantity of damping material is disposed within 5 said space between said third region and said tube.

23. The ultrasound transmission member of Claim 22 wherein said damping material comprises a resilient polymer.

24. The ultrasound transmission member of Claim 22 10 wherein said damping material comprises a liquid.

25. The ultrasound transmission member of Claim 22 wherein said damping material is selected from the group consisting of:

- 15 a) RTV silicone;
- b) natural rubber; and
- c) synthetic rubber;

26. The ultrasound transmission member of Claim 1 wherein said ultrasound transmission member is formed of a superelastic metal alloy.

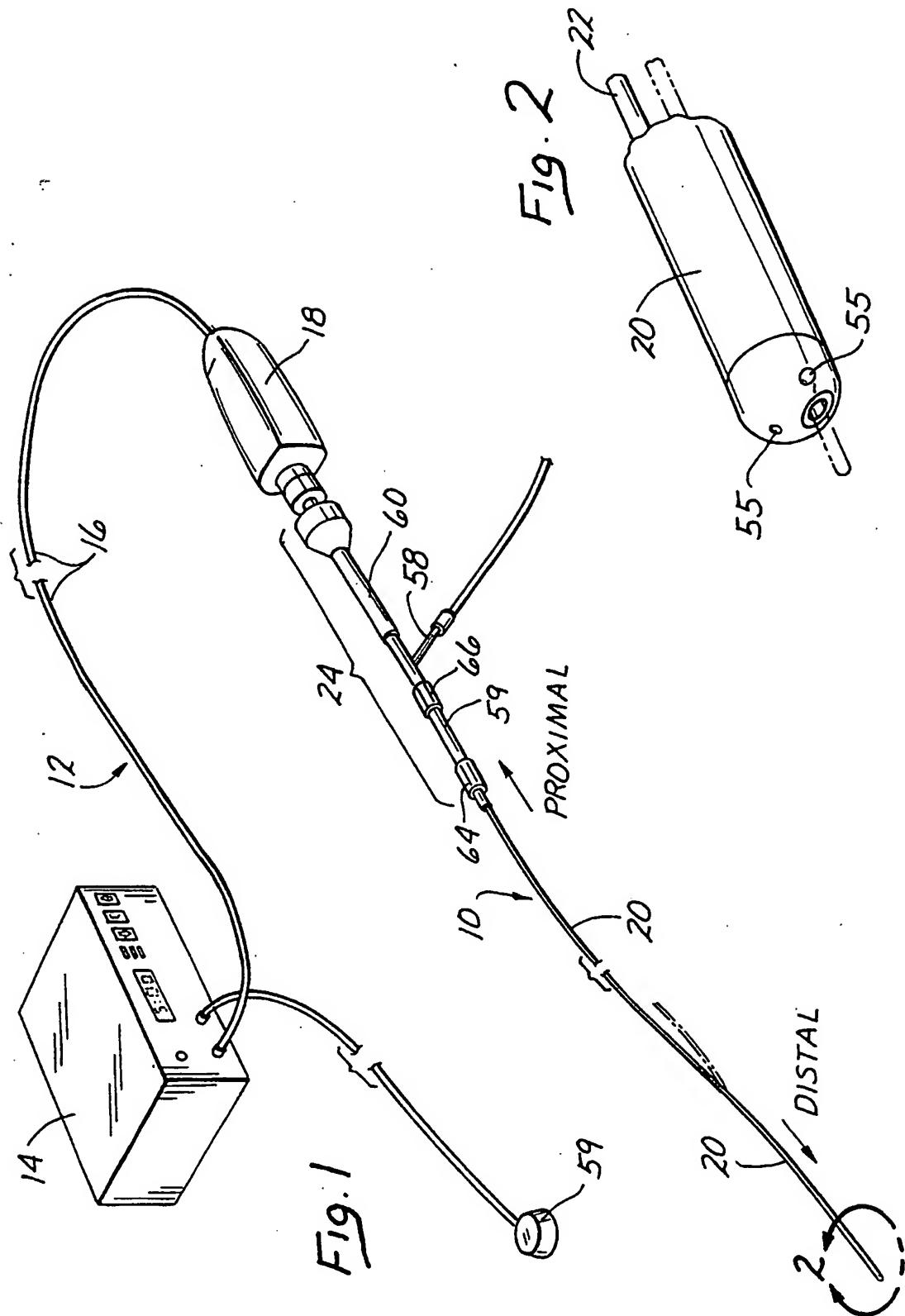
27. The ultrasound transmission member of Claim 26 20 wherein said superelastic metal alloy comprises nickel titanium alloy having 50.8 atomic percent nickel.

28. An ultrasound catheter comprising:
25 an elongate flexible catheter sheath having a distal end, a proximal end, and a hollow lumen extending longitudinally therethrough; and
the ultrasound transmission member of Claim 1 extending longitudinally through the lumen of said 30 catheter sheath.

29. The ultrasound catheter of Claim 28 further comprising:

a distal head member connected to the distal end of said ultrasound transmission member and configured

so as to be in abutting contact with the distal end of
said catheter sheath.



2 / 3

Fig. 3

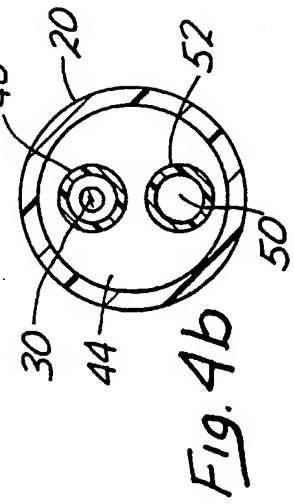
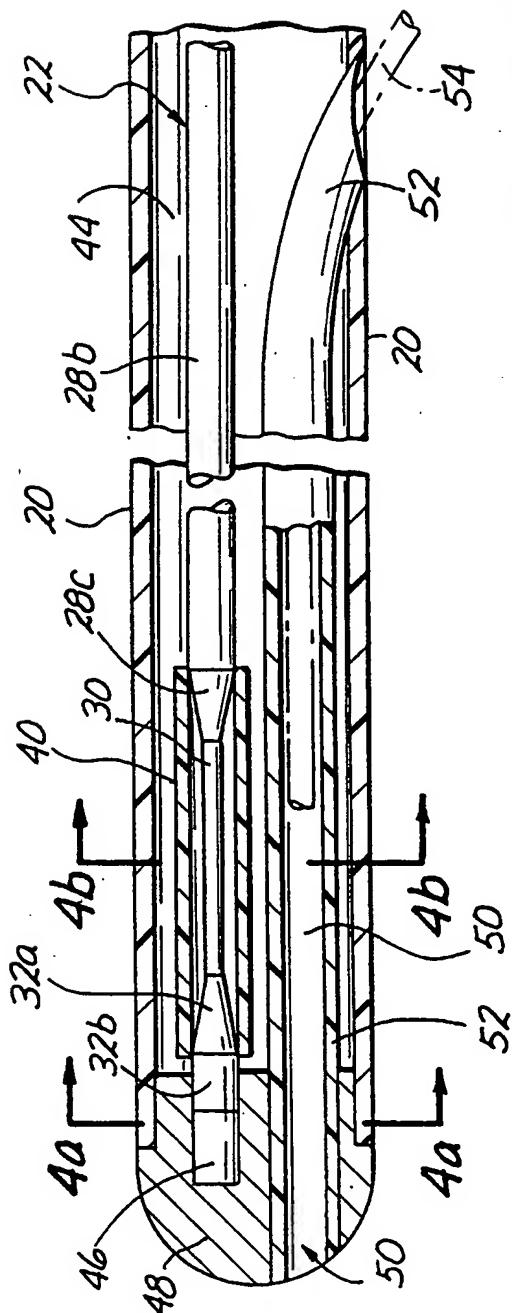


Fig. 4b

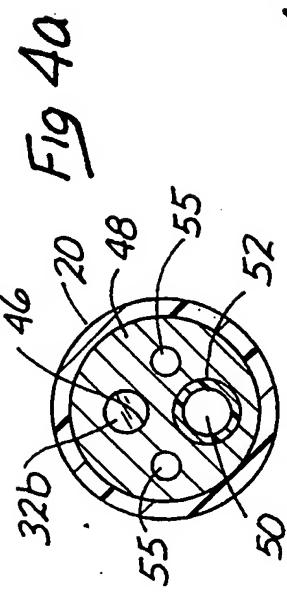


Fig. 4a

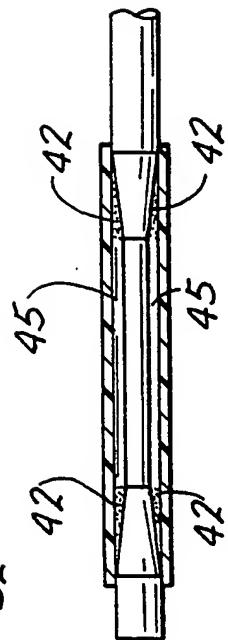
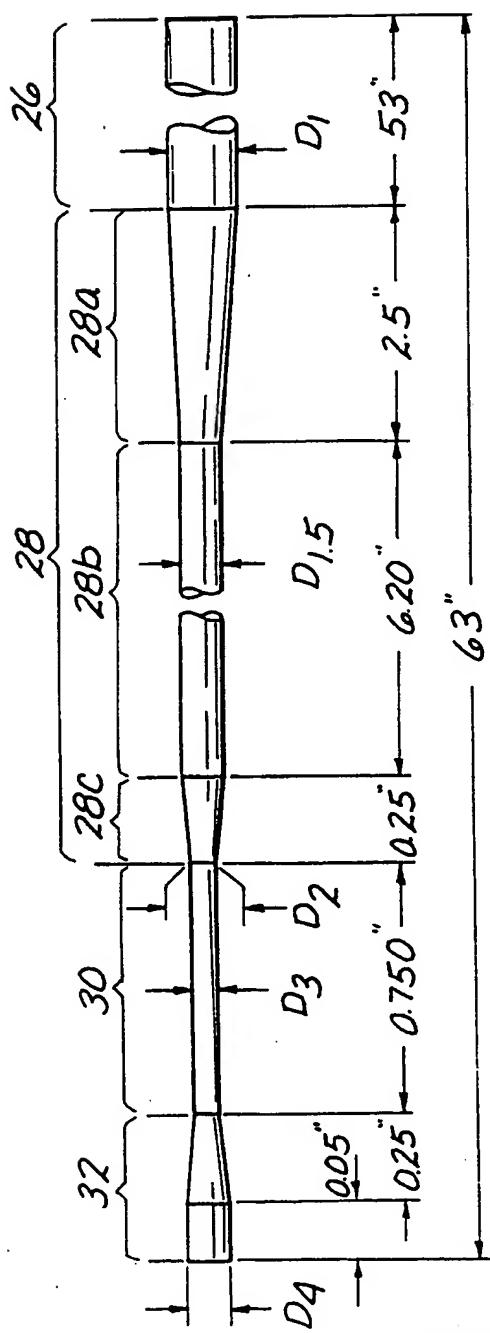
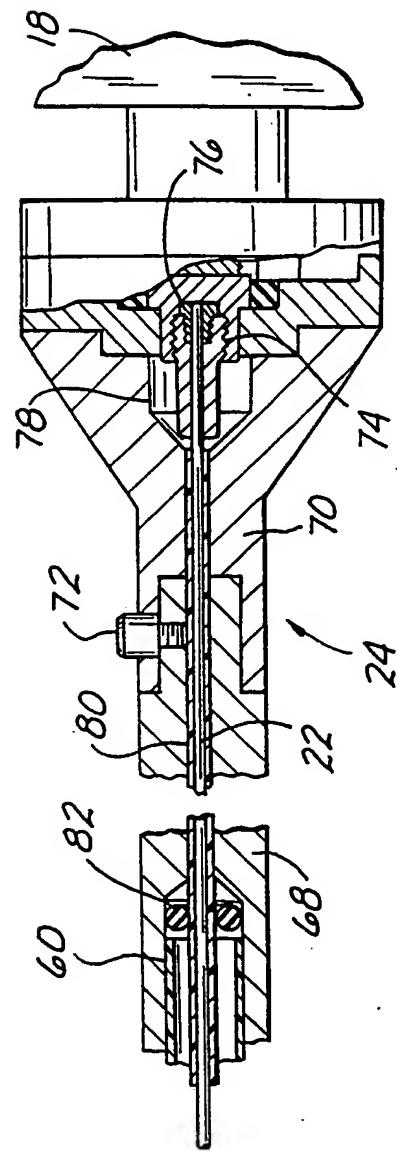


Fig. 6

3 / 3



RECTIFIED SHEET (RULE 91)
ISA/EP



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 94/11550

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22 G10K11/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B G10K B06B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,92 11815 (BAXTER INTERNATIONAL INC.) 23 July 1992 cited in the application see page 28, line 5 - page 29, line 15; figure 13 ----	1
A	WO,A,93 16646 (ANGIOSONICS INC.) 2 September 1993 see page 26, line 38 - page 28, line 6; figure 6 ----	1
A	WO,A,90 01300 (SONIC NEEDLE CORPORATION) 22 February 1990 cited in the application see page 8, line 6 - page 8, line 5; figures 5,6 -----	17

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

1 Date of the actual completion of the international search

2 February 1995

Date of mailing of the international search report

- 8.02.95

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Anderson, A

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int'l. Appl. Application No.

PCT/US 94/11550

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9211815	23-07-92	US-A-	5304115	19-04-94
		EP-A-	0566656	27-10-93
		JP-T-	6507081	11-08-94
		US-A-	5368557	29-11-94
		US-A-	5368558	29-11-94
		US-A-	5380274	10-01-95
		US-A-	5267954	07-12-93
		US-A-	5326342	05-07-94
		US-A-	5312328	17-05-94
		US-A-	5324255	28-06-94
<hr/>				
WO-A-9316646	02-09-93	US-A-	5269297	14-12-93
		CA-A-	2128006	02-09-93
		EP-A-	0627897	14-12-94
<hr/>				
WO-A-9001300	22-02-90	US-A-	4920954	01-05-90
		AU-A-	4079689	05-03-90
<hr/>				

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

GRAY SCALE DOCUMENTS

LINES OR MARKS ON ORIGINAL DOCUMENT

REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.